DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 23, 2015

Pride Mobility Product Corporation
Kimberly Elmes
Verification Manager, Quality Management Systems
182 Susquehanna Avenue
Exeter, PA 18643

Re: K143383
Trade/Device Name: Q6 Edge EM
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: June 25, 2015
Received: June 25, 2015

Dear Kimberly Elmes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143383

Device Name
Q6 Edge EM

Indications for Use *(Describe)*
The intended use of the Pride Mobility Products Corporation Q6 Edge EM is to provide mobility to persons limited to a seated position that have the capability of operating a Powered Wheelchair.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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182 Susquehanna Ave
Exeter, PA 18643
570-655-5574
FAX 570-602-4056

Exhibit 1
510(k) Summary
Pride Mobility Products Corporation
Q6 Edge EM

Submitter's Name & Address:
Pride Mobility Products Corporation
182 Susquehanna Avenue
Exeter, PA 18643
Phone: (570) 655-5574
Facsimile: (570) 602-4056

Contact Person:

Kimberly Elmes

Date Prepared:

7/14/2015

Name of Device and Proprietary Name:

Q6 Edge EM

Common or Usual Name:

Powered wheelchair

Classification Name:

Physical Medicine / Powered Wheelchair

Product Code:

ITI

Comparison to Predicate Devices:

The Q6 Edge EM is substantially equivalent to the Pride Mobility Jazzy 600 (K042612), when comparing performance, maneuverability, stability, and structure. The performance characteristics and the position of the electronics and drive mechanisms are similar to achieve the same intended use function that enables the user to maintain optimum stability without hindering performance.

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The major differences between the **Q6 Edge EM** and the Jazzy 600 (K042612) are as follows:

- The **Q6 Edge EM** has a lower weight capacity of 200 lbs versus 300 lbs for the Jazzy 600.
- The **Q6 Edge EM** is slightly larger dimensionally (47.5" L and 27.5" W) versus the Jazzy 600 (35.25" L and 23.5" W).
- The **Q6 Edge EM** utilizes Curtis electronics (previously utilized on **K112815** submission) versus Flight electronics on the Jazzy 600.
- The **Q6 Edge EM** will utilize a secondary power actuator assembly in the base to lock the casters for additional stability.

Device Description:

The **Q6 Edge EM** is a Powered Wheelchair having a digital controller, electrical system, motors, encoders, batteries, seating, actuator driven stability system, and frame. The **Q6 Edge EM** is equipped with electronic, regenerative disc brakes, off-board battery charger, removable 12 Volt U1 batteries, and front and rear caster wheels.

The **Q6 Edge EM** is designed with ultimate safety, stability, and performance in mind. The Powered Wheelchair is designed for, but not limited to Pride Mobility Products Corporation, providers/retailers and their consumers.

The **Q6 Edge EM** will incorporate all of the same features as current devices with elevation, but will utilize a secondary power actuator assembly in the base to lock the casters for additional stability. The actuator will be controlled through the current control system. The addition of the actuator assembly is the reason for this change.

The Q6 Edge EM utilizes a digital controller with a Class 1 Bluetooth®. The actual power output of the Bluetooth® device is 10 dBm (which is 10 mW) maximum output power at 50 Ohm impedance, and the maximum range is 40 m. The specific RF wireless technology type for this Bluetooth® is a Co-existence with IEEE 802.11 (AWMA, AFH). The Bluetooth® has 128-bit encryption security. The Bluetooth® allows clients to connect to a computer, smartphone, and tablet. The Bluetooth® is not active during driving or seating operation.

Intended Use:

The intended use of the Pride Mobility Products Corporation **Q6 Edge EM** is to provide mobility to persons limited to a seated position that have the capability of operating a Powered Wheelchair.

Non-Clinical Testing:

Compliance to applicable Testing Standards is as follows (Refer to 7F for FDA-3654):

Pride Mobility Products Corp.

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- RESNA WC-1:2009 - Requirements and Test Methods for Wheelchairs (Including Scooters).
- RESNA WC-2:2009 - Additional Requirements for Wheelchairs (Including Scooters) with Electrical Systems
- California Technical Bulletin 117 – Flammability Test Requirements for Upholstered Furniture
- ISO 8191- 1:1987 Furniture -- Assessment of the ignitability of upholstered furniture -- Part 1: Ignition source: smouldering cigarette
- ISO 8191-1:1988 Furniture -- Assessment of ignitability of upholstered furniture -- Part 2: Ignition source: match-flame equivalent
- AAMI / ANSI / ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity. (Biocompatibility)
- AAMI / ANSI / ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. (Biocompatibility)
- ANSI/AAMI/ISO 10993-12:2007 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.

Discussion of Clinical Testing Performed:

N/A

Conclusions:

The **Q6 Edge EM** Powered Wheelchair has the same intended use and similar technological characteristics as the Jazzy 600 (K042612), moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **Q6 Edge EM** is substantially equivalent to the predicate device, has passed all the necessary testing, and is considered to be safe for user operation